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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,085	03/11/2004	Barry N. Gellman	10124/01201	5328
30636 7590 09/25/2007 FAY KAPLUN & MARCIN, LLP 150 BROADWAY, SUITE 702 NEW YORK, NY 10038			EXAMINER NGUYEN, VI X	
			ART UNIT 3734	PAPER NUMBER
			MAIL DATE 09/25/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/798,085

Applicant(s)

GELLMAN ET AL.

Examiner

Victor X. Nguyen

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 19-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/19/2005.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. This application contains claims 19-27 drawn to non-elected inventions. In 8/20/2007, applicant elected to prosecute Group I that associated with claims 1-18. Applicant did not provide any reason as why to the restriction is improper, the election has been treated as an election **without traverse** (MPEP§813.03(a)). The requirement is deemed proper and is therefore made **Final**.

### *Drawings*

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, **a first element guide** defined in claim 1, **a sampling element actuator** defined in claim 3, **a sampling safety lock** defined in claim 4, **identification markings** as defined in claim 6, **an in-vivo tissue characterization device** as defined in claim 13 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the

Art Unit: 3734

renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3,4,6 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In claims 3-4, the disclosure does not describe a sampling element actuator and a sampling safety lock as recited. In claims 6, 13, the disclosure does not describe the first and second placeholder elements comprise identification markings and an in-vivo tissue characterization device.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is unclear from the specification and the drawing in figures 1-3 how this device works when a second place holder element is inserted through tissue to a second selected location in a patient's body, and where is the second element guide in figures 1-3 and how this second placeholder element is removably receivable in the channel.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,8,9,11,15,17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Moorman et al. (6,306,132).

Moorman et al disclose a biopsy system having the limitations as recited in the above listed claim, including: a first placeholder element 10 has a first element guide (fig. 1a) is insertable through tissue to a first location in a patient's body, where a tissue sampling element 30 is insertable to the first selected location via the first element guide for obtaining a sample of tissue and where the tissue sampling element is removable from the first element guide, where a tissue treatment element 11 is insertable to the first selected location via the first element guide, where the system further comprises a handle at 70 including a channel for receiving the first place holder element, where the system also comprises a luer 33 which is able to couple the place holder element to the channel, where a biopsy needle is able to apply suction to a sample of tissue for removal of the sample from the body (see col. 13, lines 13-17), and where the tissue treatment element comprises one of a monopolar (see col. 3, lines 22-45).

Claims 1-4,8-10,12,14 are rejected under 35 U.S.C. 102(b) as being anticipated by Weilandt. (5,788,651).

Weilandt discloses a biopsy system having the limitations as recited in the above listed claim, including: a first placeholder element 5 has a first element guide (fig.6) is insertable through tissue to a first location in a patient's body, where a tissue sampling element 4 is insertable to the first selected location via the first element guide for obtaining a sample of tissue and where the tissue sampling element is removable from the first element guide, where a tissue treatment element 3 is insertable to the first selected location via the first element guide, where the system further comprises a handle at 10 including a channel for receiving the first placeholder element, where the handle also includes a sampling element actuator 90, a sampling safety lock 105, the system further has a luer at 76, a biopsy needle at 20, and a second luer at 82.

***Allowable Subject Matter***

5. Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

***Conclusion***

Art Unit: 3734

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victor X Nguyen  
Examiner  
Art Unit 3734



VN *✓*  
9/13/2007



MICHAEL J. HAYES  
SUPERVISORY PATENT EXAMINER